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INTERMEDIATE-TERM OUTCOME AFTER LAPAROSCOPIC SACROPEXY: COMPLICATION RATE, RE-PROLAPSE RATE AND FUNCTIONAL RESULTS - A HOSPITAL BASED COHORT STUDY

Hypothesis / aims of study: Several operative approaches for the repair of a genital prolapse have been reported yet, but for the reconstitution of a physiological axis of the vagina regarding size, depth and slant a sacropexy seems to be the most adequate approach. The laparoscopic approach offers several intra-operative advantages as well as a high acceptance of patients and good convalescence after operation. Modifications of the laparoscopic approach intended an improvement of operation time and security. The German modification of laparoscopic sacropexy reduces operation time, but there is still no evidence for better long term results or for a benefit concerning complication rate. The aim of this study was to evaluate the intermediate-term outcome of the modified laparoscopic sacropexy (German method) with regard to complication rate, re-prolapse rate and patient's contentedness.

Study design, materials and methods: 132 patients suffering from genital prolapse higher than grade one POPQ (pelvic organ prolapse quantification) underwent laparoscopic sacropexy in the modification of the German method (1) during March 2005 and December 2006. In case of an extant uterus we preferred a simultaneous laparoscopic supracervical hysterectomy (n=62). Anterior and posterior colporrhaphia lateral repair and anti-incontinence operations were performed simultaneously if necessary. Perioperative single shot antibiotics were applied routinely. All patients were asked retrospectively in a questionnaire about urinary incontinence including urge and stress symptoms before and at least one year after operative repair. Subsequent operations after prolapse repair and de novo descensus problems were requested. Additionally patients were asked to evaluate their contentedness with the operative result in a rating scale (0 = worst result, not content, 10 = best result, maximum content). Patients who reported de novo symptoms or re-prolapse were re-examined. Operative result respectively degree of re-prolapse was evaluated using the POPQ-system. Intra- and postoperative complications including infection, ileus, bleeding etc were analysed using the medical records as well as the electronic data base (Care Center Siemens®). Preoperative medical records were also used to assess whether symptoms occurred de novo. Statistic basic data such as response rate, mean follow-up time and age were determined.

Results We had a response rate of 84 % (n=111). The mean follow-up interval was 22.2 month (range 13-34 month). Mean age at operation was 58.9 years (31-83 years). 4.5 % of our patients suffered from a chronicle infection of urinary tract preoperatively and were treated with antibiotics before operation. We had no intra-operative lesions. According to the operation reports mean blood loss was 125 ml (range 20-350 ml). None of our patients needed blood transfusion. 12.6 % (n=14) of our patients underwent subsequent operation. Table 1 shows the details of subsequent operation. Those patients who underwent subsequent operations without re-prolapse, showed a good sacropey result. The Vipro-mesh® provided a matrix for the invasion of fibrocytes and constituted a restiform connective tissue (fig.1). Postoperative complication rate related to ileus and infections. One patient (0.9 %) returned six month after operation suffering from a mechanical ileus. Small intestine was distorted under the sacropexy mesh and necrotic parts had to be removed over the length of 15 cm. Mesh was not removed, but peritoneum was sutured closely to recover the mesh. We had a postoperative infection rate of 11.6 % (n=13). Sub-analysis with regard to aetiology of infection revealed a high number of lower urinary tract infection (n=8; 7. 2 %). E.coli was identified as the predominant germ. Wound infections were found in three patients (2. 6 %) with a maximum on the fifth post-operative day. There was no prevalence of a special germ. Two patients (1.8 %) returned due to an infection of the cervical stump after LASH, probably resulting from faecal bacteria's. Both patients returned ten days after operation. All infections healed without complications after application of specific antibiotics. Five patients reported postoperatively about de novo stress incontinence (4.5 %). Four of these patients underwent anti-incontinence operation about one year after descensus surgery (table 1). Four patients (3.6 %) suffered postoperatively from low graded de novo urgency. We had a re-prolapse rate of 7. 2 % (5. 4 % prolapse grade II-III (n=6), 1.8 % grade IV (n=2)). We found no correlation between re-prolapse and associated operations. De novo cysto- or rectocele respectively occurred in 1. 8 % (n=2). Mean contentedness rate was 8.3 points. 6.3 % of the patients were rather discontent (0-3 points). 58 % did not specify their disaffection, 14 % were discontent due to re-prolapse and 28 % due to incontinence problems. The subgroup suffering from de novo incontinence showed a reduced contentedness with regard to the operative result (mean 7.2 points).

Interpretation of results Intraoperative lesions and blood loss are reduced after the modified laparoscopic sacropexy compared to the open approach. A well positioned, tension free mesh combined with an intracorporal suture technique helps to prevent re-prolapses. Cervical stump provides stable tissue for lower fixation of meshes, but our data concerning re-prolapse is too small for a statistical evaluation. Wound infection and infection rate of cervical stump infection are moderate. Infections of the lower urinary tract constitute a problem after gynaecological interventions (1). Careful disinfection and early removal of catheter after operation helps to reduce infections of lower urinary tract. Peritoneum is closed in very small steps as a result of our ileus complication. We prefer the induction of a rather laminar connective tissue to a restiform tissue. Thus we changed to polypropylene meshes.
In general our patients were very content with the operative result. Nevertheless de novo incontinence reduces this success. As a result we advise our patients accented before operation about the possibility of hidden incontinence and re-prolapse rates.

Concluding message: The modified laparoscopic sacropexy (German method) shows good intermediate- term results respectively re-prolapse rate, complication rates and contentedness of patients. The preoperative risk and benefits information of any pelvic surgery should include accurate advices concerning de novo incontinence and re-prolapse rate.

	No.	Result after re-operation
Transobturatorius tape	4	3 patients rectified, 1 patient improved

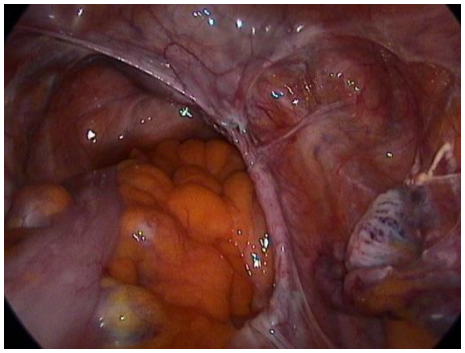

Fig.1: Result 14 month after operation

Retightening of mesh	6	All rectified
Pain	1	Nondistinctive reason
Posterior colporraphia	2	All rectified
Ovarian carcinoma	1	died 25 month later

Table 1: Details of subsequent operation after prolapse repair

	Laparoscopy (2) n=43, 20 month	Open approach (3) n=59, 6 month	German sacropexy n=111, 22 month
Intraoperative Complication	none	4.4% bleeding /3.1% bladder/0.4 nerve injury	none
Postoperative Complication			
Ileus	n.a.	2 %	0.9 %
Mesh erosion	8%	2 %	0 %
Thrombosis	n.a.	0.1 %	0%
Infection	n.a.	10 %	11.6 %
De novo cystocele	19%	6 %	1.7%
De novo rectocele	6%	4.4 %	7.7 %
Re-prolapse	5%	8 %	1.7 %
Urgency	n.a.	8%	3.6 %
De novo stress incontinence	n.a.	4.9%	4.5 %

Table 2: Comparison of classical laparoscopic approach, open approach and German modification: Complications and outcome

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Specify source of funding or grant	**No funding, no grant**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require eithics committee approval because	**We evaluated postoperative complication rates and outcomes. All patients agreed to fill in our self administered questionnaire.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**